

REMARKS

A. Status of the Claims

Claims 9-10 and 14-22 were pending at the time of the Action.

B. The Claims Are Patentable Over Fuchs in View of SU 1740002 or Buhlbacker

The Action rejects claims 9-10 and 14-22 under 35 U.S.C. § 103(a) as obvious over Fuchs *et al.* (WO 01/97634 A1) in view of SU 1740002 (as explained in the Russian Search Report) or Buhlbacker. Applicant traverses this rejection.

In making a determination as to whether a *prima facie* case of obviousness exists, the examiner should: (A) determine the scope and content of the prior art; (B) ascertain the differences between the prior art and the claims at issue; (C) determine the level of ordinary skill in the pertinent art; and (D) evaluate evidence of secondary considerations. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). Secondary considerations may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results. The currently claimed method provides surprisingly successful results in treating neurodermatitis and psoriasis that would not have been expected from the disclosures of Fuchs *et al.* (WO 01/97634 A1), SU 1740002, and Buhlbacker. Accordingly, the cited references do not render the current claims obvious.

In the working examples provided in the present specification, marked improvement in symptoms were reported in the three neurodermatitis patients given the dried mare's milk preparation (Examples 1-3, p. 24-28). This improvement was evident at the first follow-up visit at **one month** and was sustained over the course of the study. The only other measures taken by the patients were greasing ointments and oil baths. Additionally, Examples 4-6 (pages 30-34) in the specification demonstrated a clear and sustained improvement in three reported psoriasis

patients given the dried mare's milk preparation. The improvement was evident in all three patients at the first follow-up visit at six weeks.

As further evidence of the surprisingly successful results achieved by treating neurodermatitis and psoriasis according to the claimed method, Applicant provides a declaration under 37 C.F.R. § 1.132 from Norbert Fuchs ("Fuchs Declaration") describing additional studies showing that orally administering a mare's milk concentrate dried on a biologically inert, disperse matrix is therapeutically effective in treating human patients with neurodermatitis or psoriasis. The dried mare's milk concentrate used in the studies described in the Fuchs Declaration was formulated as described on page 19, line 7 to page 20, line 1 of the patent application (Fuchs Declaration, para. 4). Following a baseline examination, the dried mare's milk concentrate was administered to the patients once per day (Fuchs Declaration, para. 4). Follow-up examinations were performed approximately one month, two months, and three months after the baseline examination (Fuchs Declaration, para. 4).

In the neurodermatitis (ND) study, nine patients with moderate to severe ND were treated with the dried mare's milk composition (Fuchs Declaration, para. 5). As described in paragraphs 6 and 7 of the Fuchs Declaration, significant improvement was observed in all patients over the course of the study, with the improvement in some of the patients being evident after only about one month of treatment.

In the psoriasis study, twelve patients with psoriasis were treated with the dried mare's milk composition (Fuchs Declaration, para. 9). The mean PASI decreased from a baseline of 11.4 to 6.8 at the first follow-up examination, 4.3 at the second follow-up examination, and 3.8 at the third follow-up examination (Fuchs Declaration, para. 9). Several of the patients showed significant improvement as early as the first follow-up examination. Improvement was most dramatic in patients with the highest baseline PASI scores (Fuchs Declaration, para. 9).

The evidence in the specification and the Fuchs Declaration demonstrate that the claimed method is not only therapeutically effective, but that it is therapeutically effective in a short period of time. In contrast, Buhlbacker found that the dietetic treatment with a native mare's milk required a minimum treatment time of ***10 months***. In addition, Buhlbacker reported that mare's milk was ***ineffective*** in treating neurodermatitis if given alone. Thus, a person of ordinary skill in the art would not have expected the dried mare's milk composition described in the present specification to be effective at treating neurodermatitis and psoriasis in less than three months, and in many cases in only one month.

SU 1740002 describes the use of koumiss as a dietary supplement in the treatment of neurodermatitis and eczema. The fermentation process used to make koumiss results in a number of changes to the milk. As noted in SU 1740002, the sedative effect of koumiss, which is likely due to the alcohol content, results in more sound sleep, reduction in skin itching, and relief of high nerve excitability (SU 1740002 at page 4). In addition, SU 1740002 discloses that koumiss has antibacterial properties (SU 1740002 at page 4), which are likely attributable to the active cultures involved in the fermentation process. Thus, the teachings of Buhlbacker and SU 1740002 would likely suggest to a person of ordinary skill in the art that to enhance the beneficial effect of mare's milk one would ferment the mare's milk. There is no teaching or suggestion that drying the mare's milk would have a beneficial effect.

Fuchs discloses that highly unsaturated fatty acids are important for skin metabolism (Fuchs translation, p. 3). Highly unsaturated fatty acids occur mainly in plant oils and fish oil (Fuchs translation, p. 3). While Fuchs also discloses that milk may be added to the matrix and fatty acid mixture before drying (Fuchs translation, p. 15), there is no specific disclosure or suggestion that a milk concentrate dried on a biologically inert, disperse matrix can be used in a method treating neurodermatitis or psoriasis. Thus, in light of the teachings of Fuchs and

Buhlbacker, a person of ordinary skill in the art would have no reason to expect that the a mare's milk concentrate dried on a biologically inert, disperse matrix would be any more effective at treating neurodermatitis or psoriasis than the native mare's milk disclosed in Buhlbacker. Further in light of the teachings in SU 1740002, a person of ordinary skill in the art would more likely have been led to ferment the mare's milk in order to increase its effectiveness.

For at least the reasons discussed above, the current claims are non-obvious over Buhlbacker, Fuchs, and SU 1740002. Applicant, therefore, requests the withdrawal of this rejection.

C. Conclusion

Applicant believes this to be a complete reply to the Office Action dated January 17, 2008. The Examiner is invited to contact the undersigned attorney with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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